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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/331,554	08/23/99	ROUSSEL	HER0033

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EXAMINER

AFREMOVA, V


ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/331,554	Applicant(s) Roussel et al.	
	Examiner Vera Afremova	Group Art Unit 1651	

☒ Responsive to communication(s) filed on Nov 20, 2000.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 13-32 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 13-32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

New claims 13-32 are pending and under examination. Claims 1-12 were canceled by applicants. [paper No. 9 filed 11/20/2000].

Response to Arguments

Applicants' arguments filed 11/20/200 have been fully considered but they are not persuasive for the reasons below.

Specification

The disclosure remains objected to because of the following informalities: In response to last office action applicants amended specification to provide information with regard to current addresses of two depository collections such as "CNCM" in Institute Pasteur in France and "NCIMB" in UK. However, no information with regard to "INRA-LRTL" is disclosed by applicants on the record.

Claim Rejections - 35 U.S.C. § 112

Claims 17, 18, 22 and 23 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the same reasons as explained in the prior office action.

Claims 17, 18, 22 and 23 (as the canceled claims 8-11) are rendered indefinite by the use of internal designation numbers of strains belonging to *Propionibacterium sp.* For example, the strains disclosed in this application could be designated by some other arbitrary means, or the assignment of the strain names could be arbitrary changed to designate other strains. If either

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event occurs, one's ability to determine the metes and bounds of the claims would be impaired.

See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204,208 (CCPA 1070).

In addition, either "TL 223" (claim 17) or "TL 23" (claim 22) seems to contain some typing error.

In the response applicants seem to identify some strains which are not presently claimed, for example: TL 221, TL 227 or CNRZ 287, and, thus, adding more confusion to unappropriated use of internal designation numbers (see response page 5, last par.).

The strain P23 is identified in the specification as ITG23 which is said to be deposited in collection "CNCM" as the strain CNCM I-1804 (specification page 7, lines 19-22). Thus, it is unclear whether some difference exists or intended between strains P23, ITG 23 and CNCM I-1804 as claimed and as disclosed. Are the strains P23, ITG 23 and CNCM I-1804 identical or different?

Further, the claimed strains designated as "CNRZ" are argued as belonging to collection "INRA-LRTL" and the strains "TL" are disclosed as belonging to collection "INRA-LRTL" but this collection is not properly identified in the specification.

With regard to NCDO strain it is unclear whether the identical designation would be assigned to this strain in the collection NCIMB in UK (response page 2, lines 6-8).

And it is unclear what is designation "LS".

Amendment of the claims to refer to the deposit accession numbers of the claimed strains in International Depository in accordance to the Budapest Treaty for known in the art strains,

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when possible, and for all newly isolated/improved strains, would obviate this rejection. It is unclear as disclosed and as argued whether or not applicants' strains are old or newly claimed strains.

Deposit

Claims 17, 18, 22 and 23 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as explained in the prior office action.

Applicants argues that all microorganisms are on deposit in IDA (response page 5, par. 5). However, the collections such as "INRA-LRTL" and "National Collection of Dairy Organisms (NCDO)" are not on the current list of IDAs. MPEP 2405. Thus, the claimed strains with designation "TL" or "CNRZ" or "LS" do not appear to be readily available to the public.

And with regard to the strain ITG 23 which is disclosed as being strain CNCM I-1804 or P23, it is unknown whether this strain is available to the public at present time or who is depositor of the strain. If applicants are depositor of this strain in IDA such as CNCM, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement.

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Claim Rejections - 35 U.S.C. § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-16, 19-21, 24-26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,379,170 [A].

The claims are directed to a dietary composition and to a method of making this composition comprising propionibacteria at concentration more than 10^9 cells per gram. Some claims are further drawn to incorporation of additional bacteria such as lactic bacteria into dietary composition and to dietary composition such as cheese. The claimed propionibacteria are capable to produce particular amounts of nitric oxide at particular conditions.

The cited patent US 4,379,170 [A] is relied upon as explained in the prior office action. It teaches a composition (Swiss or Emmental cheese) and a method of making this composition comprising propionibacteria and lactic bacteria wherein concentration of propionibacteria belonging to strains P16 and P20 is more than 10^9 cells per gram (col.9, lines 45, 50-52; col. 10, lines 13).

Applicants' argument that the cited reference does not teach the ability of particular strains P16 and P20 to release nitric oxide is not found convincing. The cited compositions are considered to inherently possess ability to release nitric oxide since the cited bacteria belong to the same bacterial genus and they are used for the same purpose of preparing dietary composition such as cheese at the same amounts as required by the presently claimed composition and method

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of making the claimed dietary composition. Moreover, the cited reference teaches the use of the strain "P20" in the identical food product, for example: cheese, as presently claimed. And according to applicants' disclosure strain P20 is capable to release nitric oxide (specification page 8, lines 16-20). Thus, the cited patent appears to anticipate the claimed invention as intended.

identical
bacterium
P20

Claims 13-18 and 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,573,947 [B].

The claims are directed to a composition and to a method of making this composition comprising propionibacteria at concentration about or more than 10^9 cells per gram of the composition. Some claims are further drawn to the use of strains CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 belonging to species of *Propionibacterium acidipropionici* and to *Propionibacterium freudenreichii* in the composition and method for making the composition. Some claims are further drawn to composition being food product.

The cited US 5,573,947 [B] is relied upon as explained in the prior office action. It teaches a medicinal composition or a culture medium with antibiotics and to a method of making this composition wherein the composition comprises propionibacteria at large concentrations of about or more than 10^9 cells per gram. The cited propionibacteria belong to *Propionibacterium acidipropionici* and to *Propionibacterium freudenreichii* strains such as CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 (LABO STRADA 2502) (see table

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1 at col. 8). The cited composition is disclosed in a solid form (solid medium) or liquid form (see "dilutions" in abstract).

Applicants' argument that the cited reference does not teach the ability of particular strains to release nitric oxide is not found convincing. The cited compositions are considered to inherently possess ability to release nitric oxide since the cited propionibacteria, which substitute the major component of the cited compositions and methods, belong to identical bacterial strains as the applicants' strains CNRZ 80, CNRZ 86, NCDO 1072, CNRZ 81, CNRZ 89, CNRZ 277, and LS 2502.

Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,379,170 [A] and US 5,573,947 [B] and Balows et al. [U].

The claims are directed to a composition and to a method of making this composition comprising propionibacteria at concentration about or more than 10^9 cells per gram of the composition. Some claims are further drawn to the use of strains TL223, ITG23, CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 belonging to species of *Propionibacterium acidipropionici* and to *Propionibacterium freudenreichii* in the composition and method for making the composition. Some claims are further drawn to incorporation of additional bacteria such as lactic bacteria into dietary composition and to dietary composition

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such as cheese. The claimed propionibacteria are capable to produce particular amounts of nitric oxide at particular conditions.

The cited patent '170 [A] is relied upon as explained above. It discloses a dietary composition/method of making the composition with propionibacteria and lactic bacteria but it is lacking a particular disclosure with regard to the use of particular strains belonging to *Propionibacterium acidipropionici* and to *Propionibacterium freudenreichii*.

However, the cited patent '947 [B] teaches particular strains TL223, ITG23, CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 belonging to *Propionibacterium acidipropionici* and to *Propionibacterium freudenreichii* as explained above. The cited references are lacking the particular disclosure of some particular bacterial strains, for example: TL223 and ITG23.

Further, Balows et al. [U] teach an important role of propionibacteria in cheese industry wherein propionibacteria described as *Propionibacterium acidipropionici* and *Propionibacterium freudenreichii* are taught to be commonly used as starter cultures (pages 834 or 840). In addition, the cited reference by Balows et al. [U] teaches the ability of propionibacteria to growth on media with nitrate (page 840, table 2) and it characterize propionibacteria as denitrifying bacteria which reduce nitrate to gaseous products comprising nitric oxide or nitric oxide (page 554, par. 1; page 555, table 2; page 556, par. 2) wherein nitric oxide is an intermediate product of denitrifying bacteria including *Propionibacterium sp.*

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify composition and methods for making the composition of the cited patent '170 by using particular strains of the patent '947 with a reasonable expectation of success in producing a dietary composition because propionibacteria belonging to are commonly used in cheese manufacturing and they are known to produce gaseous products during fermentation in the media comprising nitrates as taught by Balows et al. [U]. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

With regard to the use of particular strains TL223 and ITG23 which are missing in the particular disclosure of the cited patents '170 [A] and '947 [B] it is noted that if the claimed microorganisms are not identical to the referenced microorganisms with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganisms are likely to inherently possess the same characteristics of the claimed microorganisms particularly in view of the similar characteristics which they have been shown to share. Thus the use of the claimed strains TL223 and ITG23 in the claimed composition and methods would have been obvious to those skilled in the art within the meaning of U.S.C. 103.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

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With regard to claim rejection under 35 U.S.C. 103 applicants' argument seems to be directed to the idea that the propionibacteria in the cited references are not present in compositions in particular amounts which would allow for release of nitric oxide in physiologically sufficient amounts. This is not found convincing because the cited US' 170 teaches incorporation into food compositions of identical amounts such as 6.2×10^9 plus 1.2×10^9 cells per gram which is more than 10^9 cells per gram as the presently claimed amounts. And the cited '949 teaches the use of identical strains at similar, if not identical, concentration of 10^9 cells per gram of a composition. Therefore, amounts of nitric oxide are reasonably expected to be released in identical, if not similar, physiological amounts as the presently claimed compositions particularly in view that denitrifying bacteria including propionibacteria are known to release nitric oxide as intermediate product during reduction of nitrates. And the presently claimed strains CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 have been known in the prior art [US'949] and they were taught in identical, if not similar, compositions/methods of making compositions as presently claimed. With regard to the use of strains ITG 23 (CNCM I-1809) and TL 223, it remains uncertain whether they are newly isolated/improved or already known strains of propionibacteria.

No claims are allowed.



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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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February 5, 2001.

VA.

SANDRA E. SAUCIER
PRIMARY EXAMINER

